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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/089,407	07/08/1993	PAUL A. LUCIW	0035.009	3014

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/089,407	LUCIW ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 1999*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 3/5/1999 has been entered.

The related application has been decided in Applicant's favor. Therefore, prosecution is continued and the pending rejections are set forth below.

Claims 60-76 are pending. Applicant is requested to provide a clean copy of all claims in a single section in response to this action.

Claims 60-76 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been fully considered, but are not persuasive. Applicant argues the rejection made under 35 U.S.C. 112, first paragraph, as lacking written description of the invention, by asserting that a single phrase using the term "synthetic peptide" and the disclosure of a general immunoassay constitutes written description of synthetic peptides of gag, env and pol which are to be used in immunoassays and would be immunoreactive with patient sera. This is not persuasive. Applicant further cites case law concerning the written description of claimed inventions. These arguments are not persuasive, as the issue at hand is that of written description. The determination of whether the specification provides written description of an invention is a question of fact, not a question of law. In the

previous office action, statements of fact were set forth indicating that the specification, indeed, does not set forth a written description of the invention *as now claimed.* The '501 specification describes a concept of an invention, not the invention itself. Applicant is quite right in pointing out that the "description of an invention depends on its contend in relation to the particular invention, not its length" as set forth in *In re Hayes Microcomputer Products Inc. Patent Litigation* 982 F.2d 1527 1534 25 U.S.P.Q.2d 1241 1246 (Fed Cir 1992). The position set forth in the previous office action clearly sets forth the content of the '501 specification in relation to the claimed invention, and points out the inadequacies of that disclosure. The specification describes immunoassays using undefined "fragments" of HIV gene products. The specification at no point sets forth any teaching as to synthetic peptides of env which would be useful in detecting patient sera in immunoassays. Applicant's continual reliance on the Young declaration are not persuasive for the reasons set forth in the previous office actions. Applicant devotes much of the arguments as to whether synthetic peptides were known to be used in immunoassays at the time of the invention. This is not the point of the rejection. The point is that the specification does not set forth synthetic peptides of the env gene which would be useful in immunoassays for detecting anti-env antibodies in patient sera.

Claims 60-76 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record.

Applicant's arguments have been fully considered, but are not persuasive.

In traversal of the enablement rejection, Applicant continues to rely on the Hopp algorithm as expounded in the Young declarations for support that the '501 application fully enables the production of synthetic env peptides *which would be immunoreactive with AIDS patient sera* in the claimed immunoassays. These arguments are not persuasive. The Hopp algorithm simply gives potential starting points for the synthesis of synthetic peptides. Even having potential starting points, one would have been entirely unsure as to whether that starting peptide would have allowed one to detect specific antibodies in patient sera. Applicant asserts that the specification provides "ample teachings regarding the use of peptides in immunoassays"(p6). This is not true. The '501 specification sets forth the use of recombinantly produced, allegedly full length envelope proteins, which are not synthetic peptides. In asserting that the lack of working examples in not indicative of non-enablement, Applicant again relies on the Young declaration. These arguments are not persuasive for the reasons set forth in previous discussions of the Young declaration. The examiner disagrees with Applicant's statement that the "Patent Office dismisses Applicants' contribution to this art". The contribution to the art is not minimized at all, however the contribution to the art, i.e. the cloning of a new retrovirus, is not enabling for the invention *as it is now claimed.* Applicant argues that using synthetic peptides in immunoassays was known in the art at the time of the invention. This statement is beside the point. The point is that the specification does not give one of ordinary skill in the art, synthetic peptides which would bind AIDS specific antibodies in patient sera in the claimed immunoassays. Applicant cites *In re Cavallito and Gray* in support of the breadth of the pending claims. The cited passage reads "the selection of the examples and other exemplary material

used as the disclosure to support a claim must be adequately representative of the area covered by it." The '501 specification does not disclose any examples or any other exemplary material related to synthetic env peptides which would be immunoreactive with AIDS patient sera. In regards to *Genentech*, Applicant is arguing around the point. Applicant continues to argue that the use of synthetic peptides in immunoassays was known. The point of the rejection is that the specification fails to provide synthetic peptides of env which would be immunoreactive with patient sera. The specification does not teach one of ordinary skill in the art how to identify such peptides. The state of the art in regards to immunoreactive portions of the envelope protein was not at such an advanced state that no teachings were necessary to enable the invention as now claimed. (see applicant's own arguments in traversal of the art rejections). Such teachings hardly qualify as "minor omissions" as applied by *Genentech*. Applicant continues to cite the Young declaration and its explanation of the Hopp algorithm to support the assertions of enablement. Applicant states at page 11 that "the fact that the studies cited in the Young Declaration did not employ the Hopp algorithm is irrelevant to the point which the Declaration makes." The examiner fails to see how failure to utilize a method proves its effectiveness. Finally, Applicant cites an unpublished court decision in support of enablement. Such a citation is improper, and an unpublished decision is not controlling.

Finally, in traversal of the rejection made under 35 U.S.C. 112, first paragraph, Applicant points to a portion of the specification discussing recombinantly produced peptides having various lengths. This is not persuasive, as the rejected claims set forth synthetic peptides, and not recombinantly produced peptides.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272 0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MARY K. ZEMAN
PRIMARY EXAMINER